UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

October 9, 2018
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 8.01. Other Events.

On October 9, 2018, Agile Therapeutics, Inc. (the "Company") issued a press release announcing the decision of the U.S. Food and Drug Administration's, or FDA's, Office of New Drugs, or OND, regarding the Company's formal dispute resolution request. In the OND decision, received by the Company on October 4, 2018, OND formally denied the Company's appeal and provided a path forward without the need to reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by the Division of Bone, Reproductive and Urological Products, or DBRUP. OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates generally similar adhesion performance Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated,

OND stated that the study would support the conclusion of adequate Twirla adhesion. The path forward does not address efficacy. Rather, if the wear study is successful, Twirla's safety and efficacy, including the Pearl Index, will need to be reviewed by the FDA. This is an issue that DBRUP plans to bring to Advisory Committee after the adhesion issue has been resolved. The Company plans to meet with the FDA to discuss the specifics of the proposed wear study as soon as possible. After agreeing on the parameters of the wear study with the FDA, the Company anticipates providing a further business update, which will review the Company's cash guidance and planned resubmission timeline.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated October 9, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: October 9, 2018

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: Chairman and Chief Executive Officer

Agile Therapeutics, Inc. Completes Formal Dispute Resolution Process with the FDA

PRINCETON, N.J., October 9, 2018 — Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced that it has received a response from FDA's Office of New Drugs ("OND") concerning the Company's formal dispute resolution request. The Company had appealed the decision by the FDA's Division of Bone, Reproductive and Urological Products ("DBRUP") that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval. While OND has formally denied the Company's appeal, OND provided a path forward without the need to reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by DBRUP.

OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that the Company first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. Generally, wear studies are conducted by generic companies during the Phase 1 development of transdermal products and are significantly smaller in scope and shorter in duration than typical Phase 3 contraceptive clinical trials. The wear study suggested by OND provides a path forward but does not address efficacy. Rather, if the wear study is successful, Twirla's safety and efficacy, including the Pearl Index, will need to be reviewed by FDA after the Company resubmits the NDA for Twirla. This is an issue that DBRUP plans to bring to Advisory Committee after the adhesion issue has been resolved.

"We appreciate the constructive discussions we've had with the FDA during this formal dispute resolution process. We are pleased that OND has provided a path forward, and we plan to meet with the Division to discuss the specifics of the proposed wear study as soon as possible. We look forward to resubmitting the NDA for Twirla after completion of our wear trial and welcome the opportunity to discuss the potential safety and efficacy of Twirla at an Advisory Committee Meeting," said Al Altomari, Chairman and Chief Executive Officer of Agile Therapeutics, Inc. Mr. Altomari continued, "After we agree on the parameters of the wear study, we anticipate providing a further business update, which will review our cash guidance and planned resubmission timeline."

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. Agile received a complete response letter (CRL) from the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the

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FDA had on the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. The Company initiated formal dispute resolution with the FDA on June 6, 2018 in response to the FDA's position on Twirla's *in vivo* adhesion properties. ODE III denied the Company's initial dispute resolution request on July 20, 2018. As previously disclosed, the Company then escalated its appeal to the FDA's OND. The Company believes the FDA provided guidance on a path forward for addressing the manufacturing issues related to Twirla in its minutes from the End of Review Type A meeting, received by the Company in May 2018.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla® (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15, is an investigational low-dose, non-daily, prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

Follow Agile on Linked In and Twitter: @AgileTher.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

Forward-Looking Statements

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions for Twirla. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our intention to meet with the FDA, the timing of which is subject to FDA's discretion and which may not result in a clear agreement on the issues discussed, and our belief that a reformulation of Twirla may not be necessary. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward looking statements are subject to risks and uncertainties including risks related to the FDA requiring us to reformulate Twirla, our ability to develop a reformulation that will address the FDA's concerns, including showing bioequivalence, if necessary, our ability to successfully complete the suggested wear study and that the results do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, and, the potential that

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we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, in addition to the planned correspondence regarding the design of the suggested wear study, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively

impact acceptance, review, and approval of Twirla by the FDA, including a determination by the Advisory Committee that Twirla should not be approved, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory review process for Twirla, our ability to raise capital when needed to complete the development and regulatory review process for Twirla, and unforeseen market factors or events in our clinical and manufacturing development plans and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

SOURCE: Agile Therapeutics, Inc.

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